IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC., Defendant.	**Redacted - Public Version** C.A. No. 23-975 (RGA) [redacted]

DEFENDANT LIQUIDIA TECHNOLOGIES, INC'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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Table of Abbreviations	
Liquidia Technologies, Inc.	Liquidia
United Therapeutics Corp.	UTC
Pulmonary Hypertension	PH
Pulmonary Arterial Hypertension	PAH
Interstitial Lung Disease	ILD
Pulmonary Hypertension-Interstitial Lung Disease	PH-ILD
Food and Drug Administration	FDA
Patent Trial and Appeal Board	PTAB
U. S. Patent No. 11,826,327	'327 patent
U.S. Patent No. 10,716,793	'793 patent
Full Prescribing Information for Tyvaso™ (treprostinil) inhalation solution (last revised July 2009)	2009 Tyvaso label
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21	Agarwal M, et al., *Inhaled Treprostinil in Group-3 Pulmonary Hypertension*, J HEART LUNG TRANSPLANT 2015; 34: Suppl:S343. Abstract (UTC_PH-ILD_009828)
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30	United Therapeutics Announces FDA Acceptance of Tyvaso DPI™ New Drug Application for Priority Review (June 16, 2021), available at https://pipeline.unither.com/wp-content/uploads/2021/06/2021-06-16-DPI-accept-FINAL-formatted.pdf
31	Savan Patel et al., *Robustness of Yutrepia™, a Dry-Powder Inhaled Formulation of Treprostinil, in Patient Misuse Scenarios*, CHEST (Oct. 25, 2022), available at https://investors.liquidia.com/static-files/0f869d92-5ad1-4db6-b75d-45149818ec2a
32	Liquidia Corporation Corporate Overview (June 20, 2022), available at https://www.liquidia.com/static-files/be6ab802-4090-4627-ade0-6623b6c09f24
33	United Therapeutics Corporation Reports Fourth Quarter and Full Year 2023 Financial Results (Feb. 21, 2024), available at https://ir.unither.com/press-releases/2024/02-21-2024-110027752
34	K. Parikh., et al., *Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension*, J. CARDIOVASC PHARMACOL. 67(4); 322–25 (2016) (UTC PH-ILD 010599)
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36	United Therapeutics Corporation Announces $1 Billion Accelerated Share Repurchase Program (Mar. 25, 2024), available at https://ir.unither.com/press-releases/2024/03-25-2024-110046740
37	*Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. IPR2021-00406, U.S. Patent No. 10,716,793, Jan. 8, 2022 Deposition Transcript of Dr. Aaron Waxman (Ex. 1108)
38	Physician endorsed letter advocating for the availability of Yutrepia™ to meet the need of PH-ILD patients
39	July 2009 Tyvaso Label (UTC PH-ILD 010692)

I. SUMMARY OF THE ARGUMENT

The '327 patent covers a method of treating PH-ILD with inhaled treprostinil that was publicly disclosed and practiced by physicians before the '327 patent's 2020 priority date such that, in 2018, UTC told its shareholders "This drug works" for PH-ILD. Ex. 1, 10.[1] By UTC's own admission, "there is so much robust room for growth and improvement in pulmonary hypertension[,]" and UTC "welcome[s] any new agent that can help the health of the pulmonary hypertension patient population." Ex. 2, 10. These facts warrant denial of UTC's PI Motion.

UTC seeks to preliminarily enjoin Liquidia from launching Yutrepia™ in only one of two label indications (PH-ILD) based on the '327 patent—claimed subject matter UTC has told this Court, the PTAB, and the FDA is already covered by the invalidated '793 patent. UTC is unlikely to succeed on the merits because the '327 patent is invalid and its infringement allegations are from an expert who has never seen Liquidia's dry powder inhaler. Moreover, UTC will not be irreparably harmed: (1) UTC delayed in filing this PI Motion; (2) [redacted]; (3) Liquidia can launch Yutrepia™ for PAH, negating a nexus between any alleged harm and Liquidia's supposed infringing activities; and (4) Liquidia can pay any monetary damages accrued between launch and final resolution of this case. Finally, Yutrepia™ is a PH treatment with a therapeutic benefit not provided by existing therapies. For the reasons presented herein, UTC's PI Motion should be denied.

II. FACTUAL BACKGROUND

A. Longstanding Use of Inhaled Treprostinil to Treat PH-ILD Patients

[1] "Ex." refers to exhibits in the concurrently-filed Appendix of Exhibits in Support of Defendant's Answering Brief in Opposition to Plaintiff's Motion for Preliminary Injunction.

Tyvaso was approved in 2009. Although initially approved for the treatment of PAH, physicians almost immediately began treating PH-ILD patients with Tyvaso. Channick Decl., ¶¶41-52. Multiple publications reported these positive results. Dr. Waxman, UTC's expert in the first Hatch-Waxman case, co-authored a paper in 2015 (Agarwal 2015) concluding PH-ILD could be effectively and safely treated with inhaled treprostinil. Ex. 21. Dr. Martine Rothblatt, UTC's CEO, told investors in 2018 that, based on reported results, Tyvaso worked even better in PH-ILD than in PAH patients. Ex. 1, 10. Seeking to capitalize on the known "unmistakable signals" of patient benefit in PH-ILD (*id.*), UTC conducted the INCREASE study, treating PH-ILD patients with Tyvaso in accordance with the Tyvaso label. As expected, the INCREASE study confirmed the results previously seen by physicians in their practices and in prior published studies.

B. The '327 Patent

Unsatisfied with three years of regulatory exclusivity for its PH-ILD indication, UTC sought in 2020 to patent treating PH-ILD with inhaled treprostinil—the same method already disclosed in the '793 patent and already practiced by physicians. The '327 patent, entitled "Treatment for interstitial lung disease" issued on November 28, 2023, and claims priority to two provisional applications dated April 17, 2020 and March 12, 2021. Ex. 6. For the purpose of its PI Motion, UTC asserts independent claim 1 and dependent claims 6, 9-11, and 14. Claim 1 reads as follows:

> A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration even that comprises at last 6 micrograms per breath.

Id., cl. 1. Dependent claim 6 requires that the administration of treprostinil "provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease." *Id.*, cl. 6.

Dependent claims 9-10 require providing "a statistically significant improves [sic] of forced vital capacity (FVC) in the patient" after certain time intervals. *Id.*, cls. 9-10. Dependent claims 11 and 14 require that the administration be performed with a pulsed inhalation device. *Id.*, cls. 11, 14.

III. NATURE AND STAGE OF THE PROCEEDINGS: UTC KNEW LIQUIDIA PLANNED TO LAUNCH IN PH-ILD

In 2021, UTC obtained approval for a second Tyvaso indication, PH-ILD, and knew its regulatory exclusivity would expire on March 31, 2024. D.I. 8, ¶12. UTC also knew, as of July 27, 2023, that Liquidia amended its Yutrepia™ NDA to add PH-ILD and received a Paragraph IV Notice Letter asserting that the then-listed patents for Tyvaso were invalid and/or not infringed. D.I. 27-1, Ex. 1, 1. UTC filed this suit on September 5, 2023, asserting the '793 patent, and representing to the Court that the '793 patent covers the new Yutrepia™ indication: "[p]ulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability."[2] D.I. 1, ¶4. On November 28, 2023, the '327 patent issued, and UTC amended its complaint adding the '327 patent on November 30, 2023. D.I. 8. In November 2023, UTC requested Liquidia provide advance notice of its launch of Yutrepia™ so UTC could have time to file a PI Motion and propose a briefing schedule. During a December 6, 2023 meet-and-confer, Liquidia gave notice that it intended to launch Yutrepia™ for all approved indications upon final FDA approval once UTC's regulatory exclusivity expired. *See* Ex. 3, 1. [redacted] Ex. 4, 12:10-13:19. Despite knowing months in advance it would file its PI Motion, UTC did not inform Liquidia of its intent to file until February 21, 2024. *See* Ex. 5, 2.

Since then, based on the Federal Circuit's affirmance of the PTAB's invalidation of all

[2] UTC's counsel, via email, confirmed that it brought suit based on patents it had a "good faith" belief were infringed. D.I. 12-1, Ex. 42 at 1.

'793 patent claims (*see United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755-RGA, D.I. 461-62, 465, 466 (D. Del.)), UTC dismissed its '793 patent infringement claims on January 22, 2024 (D.I. 17), and the Court granted Liquidia's Rule 60 motion and lifted its injunction based on the 793 patent (*see United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755-RGA, D.I. 479 (D. Del.)).

On February 20, 2024, UTC filed an Administrative Procedure Act case demanding that the FDA retract its acceptance of Liquidia's NDA amendment to add the PH-ILD indication. *See United Therapeutics Corp. v. FDA*, No. 24-cv-484, D.I. 1 (D.D.C.). In that case, on March 4, 2024, UTC filed another TRO/PI to enjoin the FDA from granting final approval for the PH-ILD indication, which was denied from the bench on March 29. *See United Therapeutics Corp. v. FDA*, No. 24-cv-484, D.I. 14 (D.D.C.).

IV. ARGUMENT

"[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Intel v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). Plaintiff has the burden to prove: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *see also Biogen Inc. v. Sandoz Inc.*, No. 1:22-cv-01190-GBW, 2023 WL 7130655, at *2 (D. Del. June 29, 2023). "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Waters Corp. v. Agilent Techs. Inc.*, 410 F. Supp. 3d 702, 707 (D. Del. 2019) (citation omitted). "[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm." *Amazon.com*, 239 F.3d at 1350. Thus, "[w]hile granting a preliminary

injunction requires analysis of all four factors, a trial court may . . . deny a motion based on a patentee's failure to show any one of the four factors—especially either of the first two—without analyzing the others." *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002) (internal citations omitted).

A. The Identified Claims of the '327 Patent Are Invalid

A patentee seeking a preliminary injunction "bears the burden of establishing a likelihood of success on the merits with respect to the patent's validity." *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007). The accused infringer need only raise a "'substantial question' concerning validity, enforceability, or infringement" to defeat a preliminary injunction motion. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997) (vacating the grant of a preliminary injunction because defendant raised a substantial question of validity of the asserted patent); *Entegris*, 490 F.3d at 1351; *Ingevity Corp. v. BASF Corp.*, No. 18-cv-1391-RGA, 2019 WL 2356978, at *2 (D. Del. June 4, 2019) (denying preliminary injunction because the "Defendant has raised a substantial question of invalidity based on indefiniteness."). The "substantial question" standard is "lower than what is required to prove invalidity at trial." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009).

1. The '327 patent is anticipated by the '793 patent[3]

"Under 35 U.S.C. § 102 a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *King Pharms., Inc. v. Eon Labs, Inc.*, 616

[3] There is a plethora of prior art invalidating the '327 patent. Channick Decl., ¶¶44-51, 66-84. These include, for instance, the 2009 Tyvaso label (Ex. 39) and the February 2017 INCREASE Study Description, which was made publicly available by UTC on clinicaltrials.gov in February 2017. Ex. 19; Channick Decl., ¶¶72-78. Dr. Channick provides his opinions as to why the 2009 Tyvaso label and the 2017 INCREASE Study Description inherently anticipated the identified claims of the '327 patent. *See* Ex. 19, 9-11; Channick Decl., ¶¶110-113.

F.3d 1267, 1274 (Fed. Cir. 2010) (internal quotation marks and citation omitted). To anticipate, a reference "does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) ("*BMS*"). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Leggett & Platt, Inc. v. VUTEk, Inc*., 537 F.3d 1349, 1354 (Fed. Cir. 2008) (citations omitted).

Claim 1 of the '793 patent reads as follows:[4]

> 1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

Ex. 7, cl. 1. The subject-matter in claim 1 is also disclosed in the '793 patent's specification. *Id.*, 7:55-59, 12:1-18:20; Channick Decl., ¶¶85-88. This Court has held, and the Federal Circuit affirmed, that "pulmonary hypertension" "includes treating all five Groups of PH." *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 624 F. Supp. 3d 436, 466 (D. Del. 2022), *aff'd*, 74 F.4th 1360 (Fed. Cir. 2023). The Court also recognized that Group 3 PH is "associated with disorders damaging the lungs." *Id.* at 465; Ex. 8, 38:3-39:15. And Table 3 of the '793 patent describes treating patients with pulmonary fibrosis, which is ILD. Ex. 7, cols. 13-14, Table 3 ("Etiology of pulmonary hypertension was classified as . . . pulmonary fibrosis (f)."); Ex. 9, 179:21-183:21; Channick Decl., ¶67. The Court also held that the specification of the '793 patent

[4] The '793 patent claims priority to U.S. provisional application No. 60/800,016, filed May 15, 2006, and U.S application Ser. No. 11/748,205, filed May 14, 2007. The '793 patent is pre-AIA 35 U.S.C. § 102(b) prior art at least based on its May 14, 2007 priority date.

"enables treatment of patients with Groups 1, 3, 4, and 5[,]" including the specific drug, conditions to treat, dosages (15-90 µg), and mode and method of treatment (1-3 breaths by inhalation)—the same dosing now claimed in the '327 patent. *United Therapeutics*, 624 F. Supp. 3d at 468; Ex. 9, 189:9-192:25; Channick Decl., ¶¶63-68; Ex. 10, 637:13-638:3; *see also* Ex. 11, ¶¶337-338. There is no dispute that the '793 patent discloses pulsed inhalation devices and [redacted] Ex. 7, 7:7-49, cls. 3-4; Ex. 12, ¶¶34, 46; Ex. 11, ¶268; Channick Decl., ¶¶97-99.

To the extent UTC contends the '793 patent does not disclose improving exercise capacity (*see* D.I. 26, 10), they are wrong because [redacted] Ex. 13, 5-6 (emphasis added); *see also* Ex. 14, 61-62 (UTC informing the PTAB that the '793 patent claims satisfy a long-felt but unmet need to treat primary fibrosis patients, *i.e.*, PH-ILD patients)[5]; [redacted] "new indication" covered by the '793 patent is directed to improving exercise capacity in PH-ILD patients. Ex. 15, 1; Channick Decl., ¶91. Any allegation that the '793 patent only discloses hemodynamic data does not negate its anticipatory effect, because [redacted] *See* Ex. 11, ¶277; Ex.

[5] Dr. Nathan's assertion that "the results of the INCREASE study came as a surprise to many in the field" (D.I. 28, ¶214), is not accurate in light of UTC's statement to the PTAB that the prior art '793 patent satisfied the long-felt and unmet need for a PH-ILD treatment. Dr. Nathan's testimony in this proceeding is also inconsistent with public statements he's made about the prior art and the use of inhaled treprostinil to treat PH-ILD. *See* Channick Decl., ¶¶125-132.

16, ¶¶60-61; Ex. 17, ¶¶73-75; Ex. 18, 57:5-60:2; Ex. 37, 40:12-14, 42:14-22, 152:1-8. Thus, as confirmed by UTC's statements to both this Court and other government agencies, a POSA considering the '793 patent would understand it to teach every limitation of claims 1, 11, and 14 of the '327 patent. Channick Decl., ¶¶82-99.

To the extent UTC contends the '793 patent does not explicitly anticipate the claims of the '327 patent, those claims are inherently anticipated. Channick Decl., ¶¶84-96; *Atlas Powder Co. v. IRECO, Inc.,* 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("[T]he discovery of a previously unappreciated property of a prior art composition, . . . does not render the old composition patentably new to the discoverer."). The '793 patent discloses administering the same drug (treprostinil), by the same route of administration (inhalation), in the same dose range (15 to 90 µg), delivering the same dose per breath (at least 6 µg per breath), to the same group of patients (PH Group 3 and specifically patients with primary fibrosis) as claimed in claim 1 of the '327 patent. Ex. 7, 7:55-64, 9:36-48, cols. 13-14, Table 3; Channick Decl., ¶¶64-65. The results identified in claims 1, 6, and 9-10 will necessarily and inevitably flow from practicing the '793 patent. *See* Ex. 11, ¶277; Ex. 16, ¶¶60-61; Ex. 17, ¶¶73-75; Ex. 18, 57:4-60:2; Ex. 37, 40:12-14, 42:14-22, 152:1-8, Channick Decl., ¶¶83-96. Indeed, UTC's prior assertion that Liquidia's inclusion of the PH-ILD indication on the Yutrepia™ label induces infringement of the '793 patent proves the '793 patent anticipates. *See BMS*, 246 F.3d at 1378 ("it is axiomatic that that which would literally infringe if later anticipates if earlier.").

The inherent properties of inhaled treprostinil are demonstrated by UTC's INCREASE study. The INCREASE study investigated Tyvaso for PH-ILD and demonstrated improvement in exercise capacity, a statistically significant reduction in an ILD exacerbation, and improvement in FVC. Ex. 20, 1; Channick Decl., ¶¶88-110. [redacted]

[redacted] Ex. 9, 120:2-121:2. Thus, the INCREASE study simply demonstrated the inherent properties of treprostinil administered in accordance with the '793 patent, at the same dose and in the same PH-ILD population as claimed by the '327 patent. *See In re Best,* 562 F.2d 1252, 1254 (C.C.P.A. 1977*); Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp.*, 86 F. Supp. 2d 433, 440-444 (D.N.J. 2000), *aff'd in relevant part*, *BMS*, 246 F.3d at 1378-80; *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *Eli Lilly & Co. v. Barr Lab'ys, Inc.*, 251 F.3d 955, 969 (Fed. Cir. 2001) (finding a patent invalid because the allegedly new property of the compound, inhibition of serotonin uptake, was an inherent property of the compound used to treat anxiety in a prior art patent).

Pointing to the INCREASE study, UTC contends that the '793 patent cannot inherently anticipate because "not all patients treated in accordance with the '793 patent necessarily experience [ ] improvement" in exercise capacity or FVC. D.I. 26, 10-11. But inherency does not require the claimed element to occur in *every* patient, and UTC cites no case supporting that proposition. Inherency only requires that the claimed element necessarily and inevitably occurs, which the INCREASE study demonstrated. Channick Decl., ¶¶88-96. Moreover, claims 6, 9, and 10 only require a statistically significant change, rendering irrelevant the "not all patient" argument. Because the INCREASE study demonstrates the inherent properties associated with practicing the '793 patent, claims 1, 6, 9-10, 11 and 14 of the '327 patent are inherently anticipated, and denial of UTC's PI Motion is warranted.

2. The '327 patent is obvious over the '793 patent in combination with Agarwal 2015 and Saggar 2014

A patent that merely combines "familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*,

550 U.S. 398, 416 (2007); *Q.I. Press Controls, B.V. v. Lee*, 752 F.3d 1371, 1379 (Fed. Cir. 2014). When obviousness is based on a combination of prior art references, a patent challenger must demonstrate "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention[.]" *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). A motivation to combine need not be expressly stated in one or all of the references used to show obviousness, but instead "may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006); *see also Alza Corp. v. Mylan Lab'ys, Inc.*, 464 F.3d 1286, 1290-91 (Fed. Cir. 2006). Also, "the patent challenger [must] prove that the skilled artisan would have had a reasonable expectation of successfully achieving the claimed invention from the combination [of prior art]." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021); *see also Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014) ("Conclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success."). The disclosure of the '793 patent is discussed in detail in §IV.A.1, above. *See also* Ex. 11, ¶277; Ex. 16, ¶¶60-61; Ex. 17, ¶¶73-75; Ex. 18, 57:5-60:2; Ex. 37, 40:12-14, 42:14-22, 152:1-8; Channick Decl., ¶¶82-99. Agarwal 2015 is a paper co-authored by Dr. Waxman, a co-lead on the INCREASE study and UTC's expert witness in the earlier Hatch-Waxman lawsuit. Ex. 21; Channick Decl., ¶¶76-78. Agarwal 2015 specifically discloses treating PH-ILD patients with inhaled treprostinil (Tyvaso), using at least 3 breaths with at least 6 µg per breath, for a total of 18 µg of treprostinil, and demonstrating statistically significant improvement in exercise capacity as measured by the 6MWD test, rendering claims 1, 6, 11 and 14 obvious. Ex. 21; Channick Decl., ¶¶77-78, 111-115, 130-131, 135. With respect to the FVC of claims 9 and 10, Saggar 2014

discloses improvement in FVC in PH-ILD patients upon administration of treprostinil. Ex. 22, 125; Channick Decl., ¶132-134.

A POSA would have been motivated to combine the teachings of the '793 patent, Agarwal 2015 and Saggar 2014 because they are directed to the same field of study, PH and PH-ILD, in the same patient populations, using, with respect to the '793 patent and Agarwal 2015, inhaled treprostinil with similar dosing regimens. Channick Decl., ¶¶116-121. POSAs were already successfully using Tyvaso in PH-ILD patients and combining these references simply reflects what was being done in practice. Channick Decl., ¶¶117-118; Ex. 34, 1, 5, 9; Ex. 35, 1-2.

The prior art also discloses that a POSA would have a reasonable expectation of successfully treating PH-ILD, including improving exercise capacity, and a statistically significant improvement of at least one exacerbations of the interstitial lung disease as well as FVC.[6] Channick Decl., ¶¶116-121. The INCREASE study co-leads, Drs. Waxman and Tapson, believed Agarwal 2015 and other publications provided justification to conduct a larger clinical trial in PH-ILD, and the INCREASE study paper referenced Agarwal 2015 as a basis to conduct the larger Phase III study, as did UTC's INCREASE protocol. Ex. 9, 202:13-209:7; Ex. 23, at UTC_PH-ILD_010791; Ex. 24, 19-22. Dr. Rothblatt also told shareholders in 2018 that, based on investigator-led studies in PH-ILD and payors covering off-label use of Tyvaso, they "were able to enable some WHO Group III patients to benefit, there were unmistakable signals [from] some of the leading physicians in the field[,]" including Dr. Waxman "who said to UT, 'This drug

[6] For purposes of Liquidia's opposition only, it does not raise the issue of inequitable conduct. However, while UTC focuses on its "burying" of the '793 patent (D.I. 26, 14-15), it and Dr. Nathan ignore the materiality of its failure to disclose to the examiner during prosecution of the '327 patent: UTC's identification of the PH-ILD indication in the Tyvaso label and its representation to the PTAB that the '793 patent satisfies a long-felt, but unmet need for a treatment of PH-ILD. Ex. 14, at 61-62; D.I. 12, ¶¶69-80.

works.' In fact, they believe [Tyvaso] works even better in that [PH-ILD] indication than in the Group I indication in terms of, at least, exercise ability that they saw in their patients . . . ." Ex. 1, 10. Dr. Rothblatt also admitted to seeing posters on the use of Tyvaso in PH-ILD, that provided the statistical support to conduct the INCREASE PH-ILD study. *Id.* UTC's admissions establish expectation of success and, moreover, the mere fact that UTC even conducted a clinical trial using Tyvaso to treat PH-ILD is further evidence that POSAs would have a reasonable expectation of success. *See In re Montgomery,* 677 F.3d 1375, 1382-83 (Fed. Cir. 2012).

Dr. Nathan believes a reasonable expectation of success requires a full Phase III, randomized clinical trial with results. D.I. 28, ¶¶207-208; Ex. 9, 163:16-165:6. Dr. Nathan applies too high a standard. *See Hoffman-La Roche*, 748 F.3d at 1331. Regardless, his opinion directly contradicts what his INCREASE co-leads believe and what UTC told the world in 2018, before the results from INCREASE were obtained—"This drug works." Thus, POSAs would have been motivated, with a reasonable expectation of success, to combine the '793 patent with Agarwal 2015 and Saggar 2014 to obtain the claimed invention of the '327 patent, raising yet another substantial question as to the validity of this patent.

3. Yutrepia™ does not infringe the identified claims

For induced infringement, the plaintiff must establish "that the defendant possessed specific intent to encourage another's infringement[.]" *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (internal quotation marks omitted). When a plaintiff relies on a drug label to show intent, "[t]he label must encourage, recommend, or promote infringement." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (citations omitted). Further, "[t]he FDA-approved label for an approved drug indicates whether the FDA has approved a particular method of use for that drug." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1322 (Fed. Cir. 2012). Liquidia has raised a substantial question as to the validity

of the asserted '327 patent claims. Because Liquidia cannot infringe an invalid claim, Liquidia has also raised a substantial question as to whether it induces infringement, warranting denial of UTC's PI Motion. *See Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 644 (2015) ("[I]f at the end of the day, an act that would have been an infringement … pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

a. Liquidia does not induce infringement of claims 9 and 10

UTC argues that Liquidia infringes claims 9 and 10 because "the INCREASE study on which Yutrepia's label relies shows that patients experienced a statistically significant increase in FVC after both 8 and 16 weeks[.]" D.I. 26, 8. [redacted] *See* Ex. 25; Channick Decl., ¶143-145. Because improving FVC is not FDA-approved, [redacted] and thus Liquidia cannot induce infringement. *See Bayer Schering Pharma*, 676 F.3d at 1322 (because nothing in the label "provide[d] any safety or efficacy information associated with the possible use of [the drug] in treating patients who are in need of those effects[,]" there was no suggestion to induce another's direct infringement). [redacted] because the FDA labeling regulations state that implied uses are not approved uses. *See id.*, at 1322-323 (citing 21 C.F.R. § 201.57, indications or uses "must not be implied or suggested in other sections of the labeling if not included in [the Indications and Usage section].") For these reasons, Liquidia has raised a substantial question as to infringement of claims 9 and 10.

b. Yutrepia's™ DPI is not a pulsed inhalation device

Dependent claims 11 and 14 require a "pulsed inhalation device" and a "pulsed inhalation device [that] is a dry powder inhaler," respectively. UTC's infringement argument is premised entirely on the testimony of its expert, Dr. Nathan, (D.I. 26, 8-9; D.I. 28, ¶¶145-150), but [redacted]

[redacted] Ex. 9, 62:9-63:5. Dr. Nathan's opinion is based solely on the '327 patent language that "a pulsed inhalation device, ***may be*** a dry powder inhaler[.]" Ex. 6, 21:6-14 (emphasis added). That **some** dry powder inhalers may be pulsed inhalation devices does not establish that the Plastiape RS00 Model 8 is a pulsed device—it is not. *See* Channick Decl., ¶¶56, 146-153. Dr. Nathan's infringement opinion is not credible, and UTC is unlikely to succeed on the merits of infringement of claims 11 and 14.

B. UTC Will Not Suffer Irreparable Harm if an Injunction is Not Granted

"The mere possibility or speculation of harm is insufficient" to support the extraordinary relief of a preliminary injunction—the harm must be immediate and non-speculative. *See Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1380 (Fed. Cir. 2022). UTC's alleged irreparable harm is not imminent and is speculative, the PI Motion should be denied.

1. UTC's PI Motion filing delay shows any alleged harm is not imminent

"[D]elay in . . . seeking a preliminary injunction [is a] factor[] that could suggest that the patentee is not irreparably harmed by the infringement." *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325-26 (Fed. Cir. 2012). UTC knew that its PH-ILD regulatory exclusivity would expire on March 31, 2024, and knew no later than December 6, 2023, and as early as July 27, 2023, that Liquidia amended its NDA to add the PH-ILD indication and would launch upon final FDA approval. *See* § II.A, *supra;* D.I. 27-1, Ex. 1, 1; Ex. 3, 1, 4. Despite suing Liquidia in September 2023, and amending that complaint in November, UTC did not file for a preliminary injunction until February 2024. Its delay is further unreasonable because [redacted]

[redacted] *See* Ex. 9, 133:7-22; 214:23-215:16; Ex. 39 at § 2.1.

[redacted] *See* Ex. 4, 12:10-13:1.

2. [redacted] Ex. 26, 1-3, 4-6; D.I. 29, Attachment C-1 at 1-2; Kidder Decl., ¶¶32-39. [redacted] Ex. 26, 7; Kidder Decl., ¶38. In March 2024, ***after*** it filed its PI Motion, UTC's President and COO, Michael Benkowitz, told UTC shareholders that UTC will still achieve its goal of a "$4 billion run rate by mid-decade[,]" and even upon Liquidia competition, "Tyvaso will continue to be the preferred agent[,]" that "on the payor side," UTC is "feeling increasingly confident that there's not going to be a preference[.]" Ex. 27, 3, 6. And finally, on March 25, UTC announced a $1 billion "share repurchase program" that was based on "the strength of United Therapeutics' balance sheet and confidence in its near term prospects." Ex. 36, 1. [redacted] Ex. 4, 11:10-17.

[redacted]

3. There is no nexus between UTC's alleged irreparable harm and Liquidia's launch in PH-ILD

To grant a preliminary injunction, there needs to be a "sufficiently strong causal nexus" between the alleged harm and the allegedly infringing acts. *See Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). The patentee must "present[] evidence that directly ties" the alleged irreparable harm to the "infringing feature" of the competing product. *Id.* at 1375; *Biogen*, 2023 WL 7130655, at *4. UTC makes no attempt to establish this nexus and instead vaguely references "some connection" between the '327 patent and Liquidia's launch in PH-ILD.[9] D.I. 26, 19. But a connection between the '327 patent and Liquidia's alleged infringement is the wrong inquiry—"the causal nexus requirement is simply a way of distinguishing between irreparable harm *caused by patent infringement and irreparable harm caused by otherwise lawful competition*." *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1361 (Fed. Cir. 2013) (emphasis added). UTC avoids addressing the causal nexus requirement ***because there is none***. Based on [redacted] the alleged price erosion, loss of sales, reduction in R&D capabilities, and loss of goodwill are outcomes that, if they were to occur, will happen due to Liquidia's "lawful competition" in the PAH space. Kidder Decl., ¶¶60-76, 108-115.

[redacted]

[9] UTC cites numerous cases allegedly supporting harm, but they involve generic substitution of a branded product, which is not the situation here. *See Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858 (Fed. Cir. 2017); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, 2019 WL 2588450 (D. Del. June 24, 2019); *Hoffmann-La Roche Inc. v. Cobalt Pharms. Inc.*, 2010 WL 4687839, at *1 (D.N.J. Nov. 10, 2010); *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, 2016 WL 5348866 (D.N.J. Sept. 23, 2016); *Janssen Prods., L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 700 (D.N.J. 2014). *See also* Kidder Decl., ¶43. And in *Presidio Components, Inc. v. American Tech. Ceramics Corp.*, 702 F.3d 1351, 1364 (Fed. Cir. 2012), the case involved a single product that was found to infringe, whereas here, Liquidia will lawfully be on the market in PAH.

[redacted] Ex. 4, 40:6-42:7 (emphasis added). Liquidia's lawful competition in PAH alone may cause price erosion, UTC offered no evidence that any discount would be larger if Liquidia also launched in PH-ILD, and [redacted] *Id.*, 53:8-54:8, 55:13-56:19; Kidder Decl., ¶¶70-76. Additionally, UTC's alleged harm is merely speculative. [redacted] Ex. 4, 77:3-81:10. Because there is no causal nexus between Liquidia's alleged infringement and UTC's purported irreparable harm, and any harm is speculative, UTC cannot prevail on these PI prongs.

Finally, statements to UTC's shareholders from UTC's CEO, Dr. Rothblatt, destroy UTC's allegations of irreparable harm. Dr. Rothblatt admitted in 2023 that Liquidia's Yutrepia™ does "***does not challenge our projected double-digit growth***. It's because it's not a generic product, but is instead a strongly differentiated drug device product[.]" Ex. 28, 3; Kidder Decl., ¶¶43. Dr. Rothblatt also stated that "there is so much robust room for growth and improvement in pulmonary hypertension[,]" which includes PH-ILD, and that UTC "welcome[s] any new agent that can help the health of the pulmonary hypertension patient population." Ex. 2, 10; Kidder Decl., ¶42. Dr. Rothblatt added that "the experience has been that when new agents have been introduced into the market, ***it has grown the market*** for all of the existing patients." Ex. 2, 10 (emphasis added); Kidder Decl., ¶42. [redacted] Ex. 26, 1-3, 4-6. UTC should be held to its word—Liquidia's launch in PH-ILD will not imminently and irreparably harm UTC.

[10] UTC cites *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir. 2012), but Celsis *actually* modified its pricing [redacted]

UTC and Dr. Selck also assert that Liquidia's launch in PH-ILD will result in loss of sales and market share. D.I. 26, 17-18; D.I. 29, ¶85. [redacted] Ex. 26, 1-2, 7; Kidder Decl., ¶32-37. Moreover, in assessing Yutrepia™'s impact on PH-ILD, Dr. Selck assumed each sale of Yutrepia™ for PH-ILD would come directly from a patient treated with Tyvaso. D.I. 29, § 4.3. [redacted] And Dr. Rothblatt confirmed that when new products are introduced, "it has grown the market . . . ." Ex. 2, 10. Dr. Selck has no sound basis to assume ***all*** Yutrepia™ sales in PH-ILD will come at the expense of Tyvaso. Kidder Decl., ¶70-76.

UTC's alleged loss of R&D spend is premised on allegations of price erosion and loss of sales that, for the reasons discussed above, are speculative at best. D.I. 26, 18; Kidder Decl., ¶¶60-76 ,108-111. Based on UTC's market dominance, there is no evidence that Liquidia's launch in PH-ILD will irreparably harm UTC's goodwill or reputation, and UTC has said as much in March 2024. Ex. 27, 3, 6; Kidder Decl., ¶¶112-115.

4. Liquidia can compensate UTC for any monetary losses

UTC asserts that Liquidia will be unable to compensate UTC for any monetary loss. D.I. 26, 18-19. UTC overlooks the fact that Liquidia is not enjoined from launching Yutrepia™ for

the PAH indication and Dr. Selck excluded these monies from his assessment. D.I. 29, § 5.5; Kidder Decl. ¶122. Trial is set for June 2025, and any monetary damages would accrue for a little more than a year. D.I. 45; Kidder Decl., ¶¶117-120; Ex. 4, 143:4-153:21. Finally, Dr. Selck quantified those damages, and while Liquidia disagrees with his calculations, Liquidia's unencumbered sales in PAH can be used to pay damages if UTC were to later prevail at trial.[11] Kidder Decl., ¶¶122-126. "The availability of adequate monetary damages belies a claim of irreparable injury." *Biogen*, 2023 WL 7130655, at *4 (*quoting Takeda Pharms. U.S.A., Inc. v. Mylan Pharms., Inc.*, 967 F.3d 1339, 1349 (Fed. Cir. 2020)).

C. A Preliminary Injunction is Not in the Public Interest

UTC argues that its treprostinil products already "meet the current market need"—this is not true. [redacted] There is more need to be met. Moreover, Tyvaso DPI utilizes the Dreamboat inhalation device. *See* Ex. 29, 16; Ex. 30, 1. [redacted] Ex. 9, 128:21-130:2; Channick Decl., ¶56. Because PH-ILD impacts the lungs, patients may not be able to exert the force necessary to properly utilize the Dreamboat device. *Id.* Yutrepia™ utilizes the Plastiape RS00 Model 8 dry powder inhaler, a low resistance device that addresses the segment of the PH-ILD patient population that is unable to use the Dreamboat device. Ex. 31; Ex. 38; Channick Decl.,

[11] *Eli Lilly & Co. v. Premo Pharmaceutical Lab'ys, Inc.*, 630 F.2d 120 (3d Cir. 1980) and *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 (Fed. Cir. 2011) are distinguishable. D.I. 26, 18-19. The defendant in *Eli Lilly* "was in Chapter XI reorganization[.]" 630 F.2d at 137. The defendant in *Robert Bosch* was at "[m]oderate risk of severe financial stress, such a bankruptcy, over the next 12 months" and did not submit any credible argument demonstrating its ability to pay a damages award. 659 F.3d at 1154-155.

¶56. Liquidia noted in a 2022 presentation that Yutrepia™ could "[a]ccommodate [a] wide range of lung capacities by using a low resistance device[.]" Ex. 32, 7; Channick Decl., ¶56. And clinical evidence demonstrates that many patients who tried UTC's Tyvaso DPI device are reverting back to the less convenient Tyvaso nebulized product. Channick Decl., ¶56.

D. The Balance of Hardships Does Not Tip In UTC's Favor

Liquidia is a new market entrant, while UTC has had twenty years of market dominance and $2.33 billion in yearly revenue.[12] *See* Kidder Decl., ¶¶134-135; Ex. 33, 1. The drastic difference in size and industry influence between the two parties is yet another factor showing that UTC would not suffer irreparable harm. *See Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, C.A. No. 15-819-LPS-CJB, 2016 WL 4770244, at *25 (D. Del. Aug. 12, 2016) ("[I]t is appropriate for courts to consider the relative sizes of the parties" in recommending denial of a preliminary injunction). Moreover, because of the difficulty in diagnosing PH-ILD from PAH, as Dr. Nathan acknowledged, UTC's proposed injunction could improperly stifle Liquidia's unencumbered sales in the PAH indication. D.I. 28, ¶67; Channick Decl., ¶124; Kidder Decl., ¶135-136. This is yet another factor warranting denial of UTC's PI Motion.

V. CONCLUSION

For the reasons provided herein, and as supported by the declarations of Drs. Channick and Kidder, Liquidia respectfully requests the Court deny UTC's PI Motion.

[12] In *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456 (Fed. Cir. 1998), Abbot's (the alleged infringer) "very large presence" in its field supported an injunction. The inverse is true here.

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CERTIFICATE OF SERVICE

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